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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER				
SHAY, DAVID M				
ART UNIT		PAPER NUMBER		
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MAIL DATE		DELIVERY MODE		
10/29/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

09/507,336

**Applicant(s)**

ANDERSON ET AL.

**Examiner**

david shay

**Art Unit**

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on July 11, 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 34-36, 38, 40, 41 and 74-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-36, 38, 40, 41 and 74-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Applicant argues that “neither Saul nor Chen refer to the aspect of measuring temperature change for any purpose, as recited in the claims”, also noting that the references “do not even address the tissue characterizing aspect recited in the claims”. The examiner must respectfully disagree. The examiner must respectfully note, that the instant claims merely require that the tissue be “characterized”, the broadest reasonable interpretation of this term can include characterizing the tissue as a likely successful site for ablation, as it taught by Saul, using a non ablative level of energy which is controlled by the temperature rise measured in the tissue, which is described at column 3, line 38 to column 4, line 17) as expressly noted on the page numbered 2 of the previous office action. Saul is undeniably characterizing the tissue within the broadest reasonable interpretation of this term. Saul also measures the temperature, both during the evaluation phase (during a first period of time, where non ablating energy is used) and during the ablating phase (for a second period of time, where ablating energy is used to raise the tissue to a desired temperature).

Claims 34-36, 38, and 74-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saul et al in combination with Chen et al and Lesh. Saul et al teaches a method such as claimed except epicardial placement (see column 3, line 38 to column 4, line 17). Chen et al teaches the desirability of ablating on the epicardium or the endocardium. Lesh teaches the necessity of making transmural lesions to provide conduction block. It would have been obvious to, the artisan of ordinary skill to employ the epicardial placement of Chen et al in the device and method of Saul et al, since the device and method of Chen et al is applicable to both epicardial and endocardial treatments, or alternatively to use the low temperature and high temperature device and method of Saul et al in the device and method and device of Chen et al, since this

provides more reliable ablation of accessory pathways, as taught by Saul et al, and in either case to use an input of the tissue thickness, since this is required to determine the amount of energy required to produce a transmural lesion, without producing undesired damage in the heart, thus producing a device and method such as claimed.

Claims 40 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saul et al in combination with Chen et al and Lesh, as applied to claims 34-36, 38, and 74-77 above, and further in view of Swanson et al. Swanson et al teaches the desirability of ablating on the epicardium and that less than half the total number of electrodes can be used. It would have been obvious to, the artisan of ordinary skill to employ the method and device of Swanson et al in the combined method and device of Saul et al, Chen et al, and Lesh, since this will allow greater control of the lesion size, thus producing a method and device such as claimed.

Claims 41 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saul et al in combination with Chen et al and Lesh, as applied to claims 34-36, 38, and 74-77 above, and further in view of Ben Hain et al. Ben Hain teaches drawing tissue into a suction well prior to ablation. It would have been obvious to employ the device for and step of drawing the tissue desired to be ablated into suction surrounding the ablating elements since this allows the catheter to remain stable while the tissue is ablated, thus producing a method and device such as claimed.

Claims 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saul et al in combination with Chen et al and Lesh as applied to claims 34-36, 38, and 74-77 above, and further in view of He et al. He et al teaches determining tissue parameters by cooling the tissue. It would have been obvious to employ the device for and step of cooling the tissue since this is

equivalent to the use of heating energy to do so, as taught by He et al, thus producing a method and device such as claimed.

Applicant's arguments with respect to claims 34-36, 38, 40, 41, and 74-81 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3735